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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|-------------------------------------|---------------------------------|-----------------------------|
| 10/594,381 | 06/11/2007 | Anthony Christopher Bernard Molteno | BALD 3340 | 9392 |
| 321 | 7590 | 11/16/2009 | | |
| SENNIGER POWERS LLP 100 NORTH BROADWAY 17TH FLOOR ST LOUIS, MO 63102 | | | EXAMINER DEAK, LESLIE R | |
| | | | ART UNIT 3761 | PAPER NUMBER |
| | | | NOTIFICATION DATE 11/16/2009 | DELIVERY MODE ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspatents@senniger.com

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/594,381 | Applicant(s) MOLTENO, ANTHONY CHRISTOPHER BERNARD | |
| | Examiner LESLIE R. DEAK | Art Unit 3761 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 June 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>2/23/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites that the implant “optionally” includes an outer ridge. Such a statement fails to specifically claim the invention, since it is unclear whether such a ridge is required as part of the claimed invention. As such, the metes and bounds of the claim are unclear. Since the item is “optional,” the Examiner is interpreting the claim to NOT require the outer ridge of element c.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3, 5-7, 10, 14, 16, 18, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,750,901 to Molteno.

In the specification and figures, Molteno discloses the apparatus as claimed by Applicant. With regard to claims 1 and 5, Molteno discloses an ophthalmic implant 1 comprising a plate 2 that fits the surface of the eye, an inner ridge that defines a

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drainage region inside the ridge, a secondary drainage region (comprising the surface of the plate between the inner ridge and the edge of the plate), a hole 8 in the inner ridge that connects to drainage tube 4 (see FIG 2 and accompanying text).

With regard to claims 2-3, Molteno further discloses that the implant comprises an outer ridge 3 at the peripheral edge of plate 2 (see FIG 2).

With regard to claims 6 and 7, Molteno discloses that the implant comprises suture holes used to secure the implant, indicating that there is more than one suture hole (see column 2, lines 1-9).

With regard to claim 10, Molteno discloses that the implant is suitably dimensioned to be placed in contact with Tenon's tissue to create a valving effect (see column 2, lines 23-30).

With regard to claim 11, Applicant is setting forth the intended use of the claimed apparatus. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114.

With regard to claim 14, Molteno discloses that the implant may comprise additional ridges (see column 3, lines 13-20).

With regard to claims 16, 18, and 19, Molteno discloses that the claimed implant is inserted into the patient in the manner claimed by Applicant (see column 2, lines 1-15).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 8, 9, 12, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,750,901 to Molteno.

In the specification and figures, Molteno discloses the apparatus substantially as claimed by Applicant. With regard to claim 4, it has been held that the omission of an element and its function is obvious if the element is not desired. See MPEP § 2144.04. Accordingly, it is the position of the Examiner that it would have been obvious to one having ordinary skill in the art at the time of invention to eliminate the outer ridge disclosed by Molteno if the fluid-retention properties of the outer ridge are not desired.

With regard to claims 8 and 15, it has been held that the mere duplication of the parts of an apparatus found in the prior art is not patentably significant unless a new and unexpected result is produced. See MPEP § 2144.04 (VI)(B). It is the position of the Examiner that neither four suture holes nor multiple devices provide a new and unexpected result over the apparatus disclosed by Molteno.

With regard to claims 9 and 12, it has been held that where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from

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the prior art device. See MPEP § 2144.04(IV)(A). In the instant case, it is the position of the Examiner that since the general structure of the claimed invention is known in the prior art, it would have been within the skill of a worker in the art to adjust the size of the implant in order to create desired characteristics.

7. Claims 13 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,750,901 to Molteno in view of US 5,338,291 to Speckman.

In the specification and figures, Molteno discloses the apparatus substantially as claimed by Applicant (see rejection above).

With regard to claim 13, the prior art fails to suggest the use of the claimed materials in the device. However, Speckman discloses a glaucoma implant that may use polypropylene. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use polypropylene as disclosed by Speckman in the glaucoma implant suggested by the prior art, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. See MPEP § 2144.07.

With regard to claim 17, Speckman discloses the step of temporarily occluding a drainage tube 12 in a glaucoma treatment device with an absorbable ligature (see FIGS 4-5 and accompanying text) in order to prevent overdrainage of aqueous humor upon implantation. Accordingly, it would have been obvious to one having ordinary skill in the art at the time of invention to use an absorbable ligature to occlude the outlet tube, as taught by Speckman, in the method disclosed by Molteno, in order to prevent eye hypotony, as taught by Speckman.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
4 November 2009